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### **DETAILED ACTION**

### Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 16 April 2008 has been entered.

## Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 3. Claims 1, 3-8, 10, 11, 13, 14, and 17-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Castellano (US 6,223,786).

#### Castellano teaches:

A first syringe (16) with an integral male end portion (22) having a locking ring (20), a first syringe plunger (30); a second syringe (14) with an integral female portion

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(56) comprising an exteriorly protruding member (60) to detachably fit the locking ring with opening (60-62) to receive the male end portion (Fig 7), a second syringe plunger (64), wherein the locking ring couples the first and second syringes to allow back and forth transfer of a composition.

As to claim 3,4, the female end of the syringe 14 is considered a discharge assembly and threads are capable of connection to a needle assembly as is standard in the art. As to claim 7, see flange 24. As to claim 8, see flange 66.

# Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 15,16, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castellano as applied above.

Castellano teaches mixing a generic medication and diluents but does not teach the specific drug and diluents claimed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lyophilized leuprolide acetate with Poly (D,L-lactide-co-glycolide) (PLG) dissolved in a biocompatible solvent N-methyl 2-pyrrolidone as a simple substitution of one known device for another since it is well known in the art that leuprolide acetate is used to treat endometriosis.

6. Claims 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castellano as applied to claims above, and further in view of Kanno (US 4,629,455).

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Castellano does not teach a rotatable locking ring. Kanno teaches a rotatably coupled locking ring mounted on a medical instrument. It would have been obvious to one of ordinary skill in the art, at the time of invention to have modified the connecting structure of Castellano with the connecting member as taught by Kanno for the well known purpose of providing a male and female connection alternative that can be joined firmly with high reliability.

# Response to Arguments

7. Applicant's arguments with respect to claims 1 and 3-24 have been considered but are most in view of the new ground(s) of rejection.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/ Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767